

Application No. 09/786,435

Filed: March 20, 2001

TC Art Unit: 1645

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REMARKS

Claims 1, 5-8 and 11-18 are currently pending in the present application. The Examiner has rejected pending claims 1, 5-8 and 11-18. Applicant has amended claims 1, 5, 6, 8, 14, 15, 17 and 18. Applicant has also canceled claims 7 and 11-13. The claim amendments have support in the specification such that new matter has not been presented. In particular, the specification describes on page 5 that neuron numbers and apoptosis in, for instance, the ciliary ganglia of embryos treated with anti-transforming growth factor- β (TGF- β) demonstrated increased neuron numbers as compared to those that were untreated. Applicant submits that claims 1, 5, 6, 8 and 14-18 should be pending on entry of the above amendments.

The above amendments to the claims should not be construed as acquiescence to the rejections by the Examiner and were provided solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in the present or a separate application(s).

Applicant also requests reconsideration and withdrawal of the rejections by the Examiner in view of the remarks herein.

Claim Objections

The Examiner has objected to claims 6 and 12 under 37 C.F.R. § 1.75 as being a duplicate of claims 11 and 13, respectively. Applicant has canceled claims 11-13 such that the objections by the Examiner should be withdrawn.

Claim Rejections 35 U.S.C. § 112

The Examiner has rejected claims 1, 5-8 and 11-18 under 35 U.S.C. § 112 for allegedly reciting new matter. Particularly, the

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Examiner has opined that the requirement that the cerebral disorder is not intentionally induced was not fully described within the specification. Applicant underscores that claims 1, 5, 6, 8, 14, 15, 17 and 18 have been amended such that this requirement is not recited. Thus, Applicant respectfully submits that the rejections by the Examiner under 35 U.S.C. § 112 should be withdrawn.

Claim Rejections 35 U.S.C. § 102

The Examiner has rejected pending claims 1, 14, 15 and 18 as anticipated under 35 U.S.C. § 102 by a journal article to Logan et al. The Examiner has maintained that claims 1, 14, 15 and 18 are anticipated by International Publication No. WO 93/19783 to Logan et al. The anticipation rejections of claims 1 and 14-18 in view of International Publication No. WO 95/10611 to Melton et al. have also been maintained. Applicant responds to the rejections by the Examiner under 35 U.S.C. § 102 through remarks herein.

(A) Claims 1, 14, 15 and 18 have been rejected by the Examiner as anticipated by a journal article to Logan et al. The Examiner has alleged that Logan et al. teach the method of claims 1, 14, 15 and 18. To the contrary, Applicant underscores that Logan et al. only disclose inhibiting the **extracellular** matrix deposition activity of TGF- β . Indeed, the Examiner has noted on page 8 of the Office Action the Logan et al. suggest inhibiting the **extracellular** matrix deposition activity of TGF- β in order to enhance the functional recovery from central nervous system injury and trauma. Column 1 of page 224.

By comparison, amended claim 1 specifically requires treating damaged **neurons** with a compound that prevents neuronal **apoptosis**.

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The compound of the claimed method does **not** inhibit **extracellular** matrix deposition in order to retard scar formation. The claimed method clearly treats the **neurons** themselves by way of inhibiting the **particular** biological activity of TGF- β on the damaged neurons. Claim 1 does not so much as mention or fairly encompass inhibiting the **extracellular** matrix activity of TGF- β .

The patent laws require that a reference teach each limitation of the claims under consideration to establish anticipation *prima facie*. Nevertheless, Applicant has demonstrated that Logan et al. do not disclose or even suggest preventing neuronal **apoptosis** by inhibiting the biological activity of TGF- β on damaged neurons as required by the claimed method. Applicant submits that the above requirements of the claimed method are not so much as hinted at by the cited reference. Thus, Applicant submits that claims 1, 14, 15 and 18 are plainly not anticipated by Logan et al. Applicant also submits that the rejections by the Examiner under 35 U.S.C. § 102 should be withdrawn.

(B) Claims 1, 14, 15 and 18 have been rejected by the Examiner as anticipated by International Publication No. WO 93/19783 to Logan et al. The Examiner has contended that Logan et al. disclose the method within claims 1, 14, 15 and 18. To the contrary, Applicant underscores that Logan et al. merely disclose a method in which a tissue is contacted with an agent that inhibits the **extracellular** matrix activity of TGF- β . Page 8 at line 23. The cited reference is entirely silent regarding the treatment of damaged **neurons** by inhibiting the **biological** activity of TGF- β on the neurons as claim 1 requires.

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Furthermore, amended claim 1 specifically requires treating damaged *neurons* with a compound that prevents neuronal *apoptosis*. The compound of the claimed method does *not* inhibit *extracellular* matrix deposition in order to retard scar formation. The claimed method clearly treats the *neurons* themselves by way of inhibiting the *particular* biological activity of TGF- β on the damaged neurons. Claim 1 does not so much as mention or fairly encompass inhibiting the *extracellular* matrix activity of TGF- β .

The patent laws require that a reference teach each limitation of the claims under consideration to establish anticipation *prima facie*. Nevertheless, Applicant has demonstrated that Logan et al. do not disclose or even suggest preventing neuronal *apoptosis* by inhibiting the biological activity of TGF- β on damaged neurons as required by the claimed method. Applicant submits that the above requirements of the claimed method are not so much as hinted at by the cited reference. Thus, Applicant submits that claims 1, 14, 15 and 18 are plainly not anticipated by Logan et al. Applicant also submits that the rejections by the Examiner under 35 U.S.C. § 102 should be withdrawn.

(C) Claims 1 and 14-18 have been rejected by the Examiner as anticipated by International Publication No. WO 95/10611 to Melton et al. The Examiner has contended that Melton et al. teach the method of claims 1 and 14-18. To the contrary, Applicant submits that Melton et al. only disclose inhibition of signal *transduction* by a TGF- β -type growth factor. Page 5 at line 22. The reference is entirely silent regarding the treatment of damaged *neurons* by inhibiting the *biological* activity of TGF- β on the neurons as claim

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1 requires. Indeed, Melton et al. clearly teach that TGF- β *signals* instruct cells toward "*non-neuronal facts*" such as, for example, an epidermal fate. Page 5 at line 21. Such a teaching by Melton et al. is completely in opposite to treating a damaged *neuron*.

Furthermore, amended claim 1 specifically requires treating damaged *neurons* with a compound that prevents neuronal *apoptosis*. The compound of the claimed method does *not* inhibit a signaling *pathway* of a growth factor of the TGF- β family. Page 5 at line 16. The claimed method clearly treats the *neurons* themselves by way of inhibiting the *biological* activity of TGF- β on the damaged neurons. Claim 1 does not so much as mention or fairly encompass inhibiting signal *transduction* by a TGF- β -type growth factor or the signaling of cells toward "*non-neuronal facts*."

The patent laws require that a reference teach each limitation of the claims under consideration to establish anticipation *prima facie*. Nevertheless, Applicant has demonstrated that Melton et al. do not disclose or even suggest preventing neuronal *apoptosis* by inhibiting the biological activity of TGF- β on damaged neurons as required by the claimed method. Applicant also submits that the above requirements of the claimed method are not so much as hinted at by the cited reference. Thus, Applicant respectfully submits that claims 1 and 14-18 are plainly not anticipated by Melton et al. Applicant also submits that the rejections under 35 U.S.C. § 102 should be withdrawn.

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected claims 1, 5-8 and 11-18 under 35 U.S.C. § 103 as obvious based primarily on a journal article to

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Logan et al. The Examiner has also maintained that claims 1, 5-8 and 11-18 are obvious based on International Publication No. WO 93/19783 to Logan et al. primarily in combination with a journal article to Mattson et al. Applicant responds to the rejections by the Examiner under 35 U.S.C. § 103 through remarks herein.

(A) Claims 1, 5-8 and 11-18 have been rejected by the Examiner as obvious based primarily on a journal article to Logan et al. The Examiner has alleged that Logan et al. in combination with several references teach the method and composition of claims 1, 5-8 and 11-18. To the contrary, Applicant underscores that Logan et al. only teach inhibiting the **extracellular** matrix deposition activity of TGF- β . Indeed, the Examiner has noted on page 8 of the Office Action the Logan et al. suggest inhibiting the **extracellular** matrix deposition activity of TGF- β in order to enhance the functional recovery from central nervous system injury and trauma. Column 1 of page 224.

By comparison, amended claims 1 and 5 specifically require treating damaged **neurons** with a compound that prevents neuronal **apoptosis**. The compound simply does **not** inhibit **extracellular** matrix deposition in order to retard scar formation. The claimed method and composition clearly treat the **neurons** themselves by way of inhibiting the **particular** biological activity of TGF- β on the damaged neurons. Claim 1 or 5 does not so much as mention or even encompass inhibiting the **extracellular** matrix activity of TGF- β .

The patent laws require that a reference teach each limitation of the claims under consideration to establish obviousness *prima facie*. Nevertheless, Applicant has demonstrated that Logan et al. do not disclose or even suggest preventing neuronal **apoptosis** by

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inhibiting the biological activity of TGF- β on damaged neurons as required by the compound of claims 1 and 5. Applicant submits that the above requirements of claims 1 and 5 are not so much as hinted at by the primary reference. The other references asserted by the Examiner also do not overcome any of the deficiencies of Logan et al. so as to render claims 1 or 5 obvious. Thus, Applicant submits that claims 1, 5-8 and 11-18 are plainly not obvious based on Logan et al. individually or in combination with the other cited references. Applicant submits that the rejections by the Examiner under 35 U.S.C. § 103 should be withdrawn.

(B) Claims 1, 5-8 and 11-18 have been rejected by the Examiner as obvious based on International Publication No. WO 93/19783 to Logan et al. primarily in combination with a journal article to Mattson et al. The Examiner has alleged that a combination of the cited references teach the method and composition of claims 1, 5-8 and 11-18. To the contrary, Applicant underscores that Logan et al. merely disclose that a tissue is contacted with an agent that then inhibits the **extracellular** matrix activity of TGF- β . Page 8 at line 23. The cited reference is entirely silent regarding the treatment of damaged **neurons** by inhibiting the **biological** activity of TGF- β on the neurons as required by claim 1 and 5.

By comparison, amended claims 1 and 5 specifically require treating damaged **neurons** with a compound that prevents neuronal **apoptosis**. The compound simply does **not** inhibit **extracellular** matrix deposition in order to retard scar formation. The claimed method and composition clearly treat the **neurons** themselves by way of inhibiting the **particular** biological activity of TGF- β on the

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damaged neurons. Claim 1 or 5 does not so much as mention or even encompass inhibiting the *extracellular* matrix activity of TGF- β .

The patent laws require that a reference teach each limitation of the claims under consideration to establish obviousness *prima facie*. Nevertheless, Applicant has demonstrated that Logan et al. do not disclose or even suggest preventing neuronal *apoptosis* by inhibiting the biological activity of TGF- β on damaged neurons as required by the compound of claims 1 and 5. Applicant submits that the above requirements of claims 1 and 5 are not so much as hinted at by the primary reference. The other references asserted by the Examiner also do not overcome any of the deficiencies of Logan et al. so as to render claims 1 or 5 obvious. Thus, Applicant submits that claims 1, 5-8 and 11-18 are plainly not obvious based on Logan et al. individually or in combination with the other cited references. Applicant submits that the rejections by the Examiner under 35 U.S.C. § 103 should be withdrawn.

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CONCLUSION

In view of the remarks presented herein, reconsideration and withdrawal of the rejections by the Examiner and allowance of the application with the pending claims are respectfully requested.

The Examiner is also encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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